Serial Echocardiograms During 5-Year Follow-up After Aortic Valve Replacement In The PROACT Trial

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Objective - The Prospective Randomized On-X Anticoagulation Clinical Trial (PROACT) is an FDA IDE trial, investigating safety and efficacy of reduced anticoagulation after valve replacement with the On-X mechanical valve. Transthoracic echocardiograms performed were examined to document the long-term hemodynamic function of the valve and to determine any relationship between echo outcomes and clinical adverse events.

Methods - Serial transthoracic echocardiograms were performed in asymptomatic patients at 1, 3 and 5 postoperative years after aortic valve replacement (AVR). Hemodynamic parameters were evaluated in accordance with the international heart valve standard (ISO5840:2005). Adverse event data were compiled and adjudicated using the definitions of the AATS/STS guidance on valve studies. Follow-up was conducted under investigational device exemption (IDE) rules. Univariate analyses of echo parameters against clinical endpoints used one-way ANOVA; multivariate analyses used stepwise regression.

Results - 651 echoes were gathered on 375 patients after AVR: 325 at 1-year, 247 at 3-years and 44 at 5-years. Table 1 provides mean gradient, effective orifice area (EOA) and indexed EOA (EOAI) by valve size and postoperative interval. No significant changes over time were observed. 90% of all echoes demonstrated normal (≥ 50%) ejection fraction; less than 1% exhibited paravalvular leak (none larger than 2+). No thrombosis was found in routine echoes. The composite occurrence of bleeding and thromboembolic events or death did not correlate to valve size or any hemodynamic parameter, including EOAI. Severe mismatch (EOAI ≤0.65 cm^2/M^2) occurred infrequently: 11.5% (75/651) overall [24% (18/75) for size 19mm, 20% (33/183) for size 21mm, 7% (16/232) for size 23mm and 2% (4/161) for size 25mm].

Conclusion - The hemodynamic performance of the On-X valve is consistent over time in the absence of adverse event symptoms. No relationship between adverse events and valve size or hemodynamic characteristics was found, possibly due to low occurrence of severe patient-prosthesis mismatch and low event rates.

Table 1 - On-X Hemodynamic Results [mean (stdev) N]

Size	Mean Gradient (mmHg)			EOA (cm^2)			EOAI (cm^2/M^2)		
	1-year	3-year	5-year	1-year	3-year	5-year	1-year	3-year	5-year
19mm	11.9 (4.6) 37	12.0 (4.0) 28	10.3 (4.3) 4	1.3 (0.2) 37	1.4 (0.2) 27	1.5 (0.5) 4	0.7 (0.1) 35	0.8 (0.1) 28	0.9 (0.4) 4
21mm	10.5 (5.4) 83	12.0 (6.2) 64	10.2 (4.7) 11	1.7 (0.4) 86	1.6 (0.4) 62	1.7 (0.5) 10	0.9 (0.3) 86	0.8 (0.3) 61	0.9 (0.4) 9
23mm	8.4 (4.2) 105	9.2 (4.9) 83	8.6 (4.1) 14	2.1 (0.5) 104	2.1 (0.5) 82	2.2 (0.5) 15	1.0 (0.3) 104	1.0 (0.3) 80	1.2 (0.4) 14
25mm	6.9 (3.7) 75	6.9 (4.1) 52	4.7 (3.3) 9	2.7 (0.6) 67	2.8 (0.6) 47	2.9 (0.6) 9	1.3 (0.3) 66	1.3 (0.4) 47	1.4 (0.3) 8

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